

JUN 13 2012

**510(k) Summary**

|  |   |
|--|---|
| <b>Applicant:</b>                                | Spineology Inc.<br>7800 3 <sup>rd</sup> Street N., Suite 600<br>Saint Paul, MN 55128<br>651-256-8500  |
| <b>Contact Person:</b>                           | Bryan Becker  |
| <b>Date Prepared:</b>                            | April 9, 2012   |
| <b>Trade Name:</b>                               | Spineology PEEK Lumbar Interbody Fusion Devices   |
| <b>Product Classification and Code:</b>          | Class II Medical Device, Product Code MAX   |
| <b>Predicate Device(s):</b>                      | Spineology PEEK Lumbar Interbody Fusion Devices (K120293)   |
| <b>Reason for this 510(k)</b>                    | This Special 510(k) is to add an option 4 <sup>th</sup> marker to the front of the implant.   |
| <b>Device Description:</b>                       | The Spineology PEEK Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The device is available in a range of lengths and heights and is made of PEEK Optima LT1. The device and associated instruments are provided non-sterile.  |
| <b>Intended Use:</b>                             | <p>The Spineology PEEK Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.</p> <p>These devices may be implanted via an open or a minimally invasive transforaminal approach.</p> <p>The Spineology PEEK Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.</p> |
| <b>Summary of Technological Characteristics:</b> | The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products.  |

|                    |   |
|--------------------|---|
| <b>Testing</b>     | Static compression testing per ASTM 2077 was performed. The results showed that the device was substantially equivalent to the identified predicate devices.  |
| <b>Conclusion:</b> | The information submitted in this premarket notification supports a determination that the Spineology PEEK Lumbar Interbody Fusion Device is substantially equivalent in technological characteristics and intended use to the predicate devices. |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

JUN 13 2012

Spineology, Inc.  
% Mr. Bryan Becker  
Clinical and Regulatory Affairs Manager  
7800 3<sup>rd</sup> Street North, Suite 600  
Saint Paul, Minnesota 55128

Re: K121129  
Trade/Device Name: Spineology PEEK Lumbar Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: May 11, 2012  
Received: May 14, 2012

Dear Mr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



*for* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K 121129

## Indications for Use Form

**Device Name:** The Spineology PEEK Lumbar Interbody Fusion Device

### Indications for Use:

The Spineology PEEK Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to SI1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

These devices may be implanted via an open or a minimally invasive transforaminal approach.

The Spineology PEEK Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K121129